General

Guideline Title

Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

Bibliographic Source(s)

Guideline Status

This is the current release of the guideline.

The American Academy of Neurology (AAN) reaffirmed the currency of the guideline in January 2015.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (I-IV) are provided at the end of the "Major Recommendations" field.

Recommendations

1. Transcutaneous electric nerve stimulation (TENS) is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (Level A, 2 Class I studies).
2. TENS should be considered for the treatment of painful diabetic neuropathy (Level B, 2 Class II studies).

Definitions:

Therapeutic Classification of Evidence

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:

a. Primary outcome(s) is/are clearly defined

b. Exclusion/inclusion criteria are clearly defined
c. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias
d. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences

Class II: Prospective matched group cohort study in a representative population, with masked outcome assessment that meets a-d above OR a randomized controlled trial in a representative population that lacks one criterion a-d.

Class III: All other controlled trials including well-defined natural history controls or patients serving as own controls in a representative population, where outcome assessment is independently assessed or independently derived by objective outcome measurement.*

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

*Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data)

Classification of Recommendations

Level A = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

Level B = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if: 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Chronic low back pain
- Painful distal symmetric diabetic neuropathy

Guideline Category

Technology Assessment

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Neurology

Physical Medicine and Rehabilitation

Intended Users

Physical Therapists

Physician Assistants

Physicians

Guideline Objective(s)

To determine if transcutaneous electric nerve stimulation (TENS) is efficacious in the treatment of pain in neurologic disorders

Target Population

Adults with pain associated with neurologic disorders

Interventions and Practices Considered

Treatment with transcutaneous electric nerve stimulation (TENS)

Major Outcomes Considered

Changes in visual analog pain scale (VAS)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

2010 Guideline

A Medline search from inception to April 2009 was performed, using the terms "transcutaneous electric nerve stimulation" (Medical Subject Headings [MeSH]) and "nervous system diseases" (MeSH) or "peripheral nervous system diseases" (MeSH) or "central nervous system diseases" (MeSH), which was limited to "clinical trial, meta-analysis, practice guideline, randomized controlled trial, human." The Cochrane Library was searched using the terms "transcutaneous electric nerve stimulation" or "TENS." Inclusion criteria were clinical trials of TENS compared to placebo or to another therapy for well-defined painful neurologic disorders with more than 10 subjects. Additional articles were obtained from the bibliographies of these articles and of review articles.

2015 Reaffirmation

Medline and Cochrane databases were searched from 2009 December 30 to 2015 January 24 using the terms "transcutaneous electric nerve

stimulation," "nervous system diseases," "peripheral nervous system diseases," "central nervous system diseases," "TENS." Clinical trials of TENS compared to placebo or to another therapy for wellâ€defined painful neurologic disorders with more than 10 subjects were included.

Number of Source Documents

There were nine source documents. Eleven studies met the inclusion criteria; two studies of chronic pain were excluded because etiologies of pain were diverse, and meaningful data on any one type of pain could not be extracted from presented data.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Therapeutic Classification of Evidence

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:

a. Primary outcome(s) is/are clearly defined
b. Exclusion/inclusion criteria are clearly defined
c. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias
d. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences

Class II: Prospective matched group cohort study in a representative population, with masked outcome assessment that meets a-d above OR a randomized controlled trial in a representative population that lacks one criterion a-d.

Class III: All other controlled trials including well-defined natural history controls or patients serving as own controls in a representative population, where outcome assessment is independently assessed or independently derived by objective outcome measurement.*

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

*Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data)

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The titles and abstracts were reviewed, and articles meeting criteria were reviewed in full and assigned a class of evidence (see "Rating Scale for the Strength of the Evidence").

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

2010 Guideline

Recommendations were based on the level of evidence (see "Rating Scale for the Strength of the Recommendations"). Disagreement about the assigned level of evidence was resolved through discussion.

The Therapeutics and Technology Assessment Subcommittee adopted the definitions used in each paper for meaningful reduction in pain, realizing that this varies between treatments for acute and for chronic pain. Although the World Health Organization classifies significant pain reduction in the treatment of patients with cancer as >50% using a 100 mm visual analog scale (VAS) or a decrease to a level of 3 or less using a verbal rating scale of pain intensity from 0 to 10, the definition of meaningful pain reduction is controversial. Thus, many of the articles used a decrease of 20 mm or a 25% decrease with a baseline VAS of 50 mm or less clinically significant.

2015 Reaffirmation

An author conducted a literature search using the same criteria as presented in the original guideline. Because the guideline recommendations would not change given the new literature available, the committee voted to reaffirm the guideline, stating that the conclusions and recommendations are still valid.

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations

Level A = Established as effective, ineffective, or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

Level B = Probably effective, ineffective, or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective, or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if: 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts of this guideline have been reviewed by at least three American Academy of Neurology (AAN) committees, a network of neurologists, Neurology® peer reviewers, and representatives from related fields.

This guideline was approved by the Therapeutics and Technology Assessment Subcommittee on April 28, 2009; by the Practice Committee on July 10, 2009; and by the AAN Board of Directors on October 19, 2009.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of transcutaneous electric stimulation (TENS) in the treatment of pain in neurologic disorders

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

This statement is provided as an educational service of the American Academy of Neurology (AAN). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. No formal practice recommendations should be inferred.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

Resources

Wall Poster

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Dubinsky RM, Miyasaki J. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2010 Jan 12;74(2):173-6. [12 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2010 Jan (reaffirmed 2015 Jan 24)

Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

Source(s) of Funding

American Academy of Neurology (AAN)

Guideline Committee

Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Guideline Status

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This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

A list of American Academy of Neurology (AAN) guidelines, along with a link this guideline, is available at the AAN Web site
[   ].

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 201 Chicago Avenue South, Minneapolis, MN 55415.

Availability of Companion Documents

The following are available:

- Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders. American Academy of Neurology (AAN) summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology. 2010. 1 p. Available from the AAN Web site [   ].
- Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders. Poster. St. Paul (MN): American Academy of Neurology. 2010. 1 p. Available from the AAN Web site [   ].
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the AAN Web site [   ].

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

In addition, Chinese and Korean translations of the original guideline document, as well as a podcast are available from the *Neurology* journal Web site [   ].

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 18, 2010. The currency of the guideline was reaffirmed by the developer in January 2015 and the summary was updated by ECRI Institute on December 22, 2015.

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